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REVIEW ARTICLE

What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials

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ABSTRACT

Purpose
The systematic use of patient-reported outcome measures (PROMs) has been advocated as an effective way to standardize cancer practice. Yet, the question of whether PROMs can lead to actual improvements in the quality of patient care remains under debate. This review examined whether inclusion of PROM in routine clinical practice is associated with improvements in patient outcomes, processes of care, and health service outcomes during active anticancer treatment.

Methods
A systematic review of five electronic databases (Medline, EMBASE, CINAHL [Cumulative Index to Nursing and Allied Health Literature], PsycINFO, and Psychology and Behavioral Sciences Collection [PBSC]) was conducted from database inception to May 2012 to locate randomized and nonrandomized controlled trials of patients receiving active anticancer treatment or supportive care irrespective of type of cancer.

Results
Based on prespecified eligibility criteria, we included 26 articles that reported on 24 unique controlled trials. Wide variability in the design and use of interventions delivered, outcomes evaluated, and cancer- and modality-specific context was apparent. Health service outcomes were only scarcely included as end points. Overall, the number of statistically significant findings were limited and PROMs' intervention effect sizes were predominantly small-to-moderate.

Conclusion
The routine use of PROMs increases the frequency of discussion of patient outcomes during consultations. In some studies, PROMs are associated with improved symptom control, increased supportive care measures, and patient satisfaction. Additional effort is required to ensure patient adherence, as well as additional support to clinicians who will respond to patient concerns and issues, with clear system guidelines in place to guide their responses. More research is required to support PROM cost-benefit in terms of patient safety, clinician burden, and health services usage.

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INTRODUCTION

Anticancer treatments have brought about definite advances in patient survival rates.[1] However, treatment is associated with significant toxicity that is potentially life-threatening,[1] and can often result in poor treatment adherence, impaired quality of life (QoL), and mortality.[2,3] Systematic monitoring is crucial to detect problems, to address needs of patients, and to plan care.[4] Using patient-reported outcome measures (PROMs), "measurements of any aspect of a patient's health status that come directly from the patient,"[5] facilitates a systematic and comprehensive approach to patient assessment and identifies problems that are often overlooked within routine practice. Regularly collecting PROM data is an effective way to standardize practice and improve patient management.[4] Nevertheless, the question of whether PROMs can improve the quality of patient care, and whether this relates both to health professional engagement with them and to the system guidelines in place to guide response, remains under debate. Given the costs associated with collecting PROMs, evidence of their effect on patient outcomes (POs), processes of care (PoCs), and/or health service outcomes (HSOs) is needed.

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Previous reviews have concluded some clinically meaningful, but not always statistically significant, effects on the use of PROMs in clinical practice.[5-11] Only two of these reviews[9,11] were specific to cancer care and differed in terms of objectives, comprehensiveness, and quality. Taking into consideration the lack of clarity around the use of PROMs in cancer care, we conducted a comprehensive systematic review of all available controlled trials (CTs) to examine whether routine use of PROMs by health care professionals (HPs) can improve the quality of care patients receive during active anticancer treatment. The value of PROM use was examined through detection of positive effects on POs, PoCs, and HSOs, as suggested by statistical/clinical changes.

METHODS

We searched five electronic databases (Medline, EMBASE, CINAHL [Cumulative Index to Nursing and Allied Health Literature], PsycINFO, and PBSC) from database inception to May 2012, using a systematic strategy that was devised and refined through an iterative process (Appendix Table A1 [online-only]). Additional articles were identified through previous topical reviews.[5-11] We also examined reference lists of the articles retained for any studies that might have been overlooked. Where necessary, we contacted study authors to provide clarification on characteristics of the study samples included. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines where applicable.[12]

Study Selection Criteria

Trials were deemed eligible if they were primary or secondary reports of CTs testing PROM interventions in which PROM-generated feedback was made available to HPs or patients to improve quality of patient care; involved adult patients (> 18 years old) with cancer, irrespective of disease stage, who received any type of active anticancer treatment or supportive care, even if only part of the sample received active treatment/care but percentages were reported; were randomized CTs (RCTs) or non-RCTs; and were published in the English language with readily available abstracts. Trials were excluded if they evaluated PROMs as part of broader psychobehavioral interventions, in which PROMs were only used to evaluate intervention effectiveness; investigated the effects of a medicinal product; were conducted with survivors of cancer who were not actively receiving anticancer treatment; tested the psychometric properties of PROMs; or involved children with cancer, or survivors of childhood cancers.

Study Selection and Data Extraction Procedures

Study selection involved two stages: an initial title and abstract screening with eligibility evaluation performed by two screening groups that independently screened the retrieved records against selection criteria, and retrieving potentially eligible full-text articles, which were independently evaluated for eligibility by five reviewers. Selection of the final sample of studies was discussed until a consensus was reached. Five reviewers extracted data using forms that were specifically developed for this review, pilot tested the forms on three randomly selected studies, and refined the forms accordingly.

Risk of Bias and Methodologic Quality Evaluation

We used the Cochrane Collaboration Risk of Bias Tool[13] to evaluate six different domains of a CT: adequacy of sequence generation, concealment of allocation, blinding, completeness of follow-up, freedom from reporting bias, and other forms of bias. We evaluated each domain of bias as low risk, high risk, or unclear. Three reviewers assessed five articles each, and a fourth reviewer cross-checked the evaluations until a consensus was reached. Reviewers were not blinded to authors, institutions, or journals of publication.

Outcome Evaluation

Based on previous topical reviews,[5-11] three major outcome categories were formed: POs (ie, health status/well-being/functioning; symptom burden/distress; health-related QoL; psychological distress), PoCs (ie, patient satisfaction with treatment/care/consultation; patient behaviors/actions/adherence; patient-HP communication; patient-HP concordance in assessments; HP engagement in assessment), and HSOs (ie, patient safety; cost-effectiveness; number of contacts with clinicians; patient resources/services use). We anticipated that not all CTs would report on every outcome category or on every outcome within a specific category.

Synthesis of Results and Determination of Effect Sizes

Individual outcomes were classified according to prespecified major outcome categories, and findings were narratively synthesized. Prevalence (%) of studies examining each individual outcome and major categories was examined and plotted. Because of variability in the patient populations, outcomes assessed, outcome PROMs used, and reporting of results, we deemed a meta-analysis was not feasible. However, where enough data were available, effect sizes (ES; Cohen's d) and 95% CIs were estimated based on mean postintervention total scores of outcome measures or percentages of patients reporting specific outcomes based on specific formulas.[14,15] By convention, ES where $d \geq 0.2$ were considered small, $d \geq 0.5$ were moderate, and $d \geq 0.8$ were large.[16]

RESULTS

Search Results and Study Characteristics

Initial searches retrieved 4,997 references from electronic databases and 18 from previous published literature reviews.[5-11] Twenty-six articles[17-42] reporting on 24 unique CTs fulfilled eligibility criteria and were included in a qualitative synthesis (Fig 1). All but four trials[18,24,34,36] were RCTs, and 16 adopted a longitudinal study design (Table 1). Patient study samples varied widely in size (median, 194 individuals; range, 48 to 1,134 individuals; for a total of 6,279 individuals). HP samples varied similarly (median, 22 HPs; range, four to 262 HPs; total, n = 713), but they were reported in only 11 trials. Nine CTs tested interventions designed specifically for patients with breast,[20,22,26,27] lung,[20,29,30,33,34] or hematologic malignancies.[32] Seventeen CTs tested interventions delivered in the outpatient/ambulatory setting. Only two RCTs targeted patients with early-stage cancers.[19,22] Thirty-seven percent to 100% of patients were receiving active anticancer treatments during study participation, and these treatments were most frequently chemotherapy or radiotherapy.

In terms of intervention design, patients in the control group either received usual care only[19,21,28,34,36,41,42] or completed PROMs similar to that of the experimental group, but feedback remained unavailable to HP.[17,18,24,26,30-33,37,40] Only one three-arm RCT combined these two alternative conditions in the same design.[35,38,39] In the more diverse CTs, PROMs were completed at home by the experimental group but were not administered to patients in the control group[25,29]; were completed by all participants, but PROM summaries of the experimental group were only placed in the medical records or sent to HPs[20,23]; or were completed by patients in the experimental group only to direct further intervention based on distress expressed by a subset of the group.[20,22,27] In only five CTs did HPs follow specific guidelines to guide response to PROM feedback.[20,22,23,26,28]

Twenty-nine PROMs were administered in the reviewed trials to help deliver the interventions (Appendix Table A2). Eleven CTs relied on only one intervention PROM, seven incorporated two PROMs, and six CTs used three or more instruments.[17,18,23,24,28,42] The most frequently used PROM was the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30; n = 11). Other PROMs focused on symptom prevalence and severity (n = 11), supportive care needs (n = 8), QoL issues (n = 5), or sources of distress (n = 3). The PROMs were administered on media including electronic platforms (n = 11), paper-and-pencil tools in clinic (n = 12), take-home log books (n = 3), and mailed assessments and/or telephone interviews (n = 7; Table 1).

Risk of Bias Within and Across Studies

Two RCTs were rated as low risk in five of the seven bias categories.[26,29] Yet, bias in the design and/or reporting was present in all of the included trials (Table 2), regardless of whether patients were randomly assigned to the study

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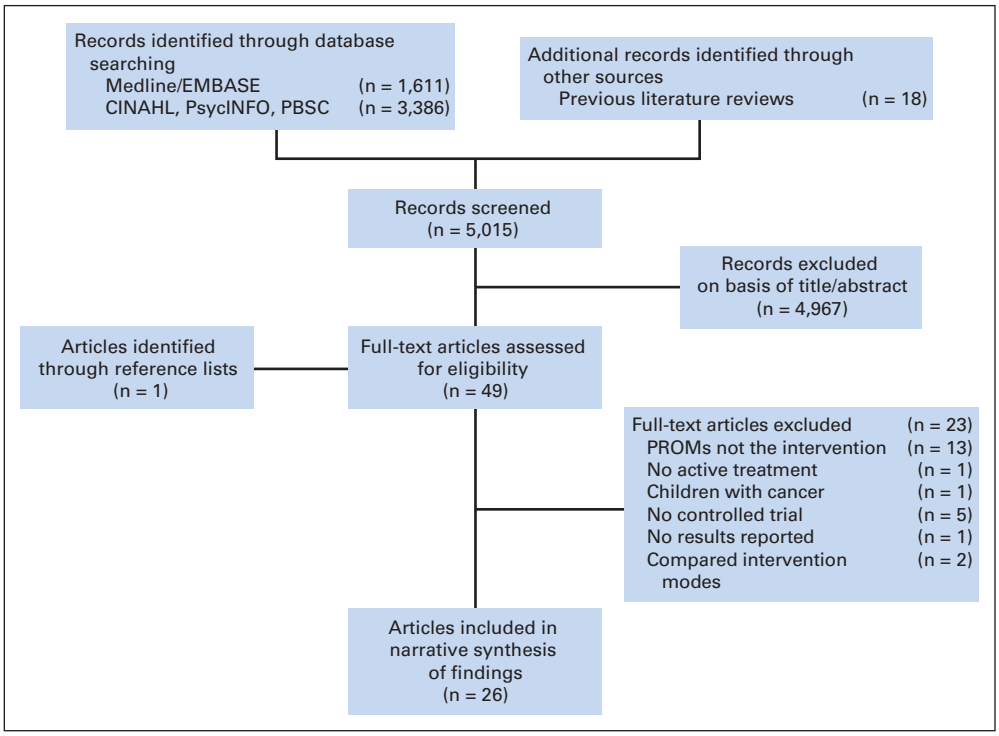

Fig 1. Diagram of the study selection process according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[12,43] CINAHL, Cumulative Index to Nursing and Allied Health Literature; PBSC, Psychology and Behavioral Sciences Collection; PROMs, patient-reported outcome measures.

condition. Only seven RCTs were rated as low risk on both the random-assignment generation process and allocation-concealment bias.[17,20,26-29,41] Conversely, all non-RCTs were consistently rated as high risk. With the exception of three RCTs,[21,22,40] performance bias was rated as high for all CTs given that blinding on the HP level was not feasible. With the exception of seven CTs,[18,25,28-30,40,41] risk of detection bias was also deemed high or unclear. Ten CTs were rated as high risk regarding attrition-related bias.[18-20,24,27,33,35,38-42] Selective outcome reporting bias was predominantly unclear (n = 18; 75%). Additional sources of bias interfered with 15 CTs. Most frequently, authors were unclear as to whether HPs who received patient feedback actually used it during consultations.

Outcomes Evaluation

POs and/or PoCs were reported as primary outcomes in 21 CTs (87.5%) and 19 CTs (79.2%), respectively; however, intervention effects on HSOs were only scarcely investigated (Table 2 and Table 3).[20,22,27,30,42] Eighteen CTs evaluated the effects of interventions in the long term (> 8 weeks), with follow-up assessments ranging in number from two to four or more that were conducted for up to 12 months (but mainly ≤ 6 months) after baseline assessment.

Patient Outcomes

Physical symptoms. Overall, positive effects with reduced symptom prevalence or severity were reported in seven CTs (six RCTs), mainly clinically and less frequently statistically significant. ES ranged widely and were mainly small-to-moderate in terms of intervention effects on physical symptom prevalence (d = 0.01 to 0.75), physical symptom severity (d = 0.0 to 0.44), psychological symptom prevalence (d = 0.07 to 0.15), psychological symptom severity (d = 0.01 to 0.30), or psychological symptom distress (d = 0.09 to 0.42; Appendix Table A3). Across CTs, patients in the experimental group reported greater reductions in symptom-threshold events and symptom interference with functioning,[40] severity of menopausal symptoms and sexual dysfunction,[22] frequency of constipation and vomiting,[25] incidence of pain[37] or fatigue,[41] debilitating symptoms,[18] and distress associated with symptoms/problems[32,41] compared with those in the control group, irrespective of cancer type or stage.

Quality of life. Survivors of breast cancer,[22] patients with nonlocalized breast cancer or colorectal cancer,[23] and groups of patients with mixed cancer diagnoses at an advanced stage[21,31,42] or at various clinical stages[24,28] had no significant postintervention effects in nine CTs (Table 2; Appendix Table A3). In terms of overall QoL, ES ranged from 0.04 to 0.59, but were mainly small in magnitude. Nevertheless, rates of diseased QoL were reduced in women with breast cancer 6 months after surgery in the experimental group compared with the control group (d = 0.35).[26] Among patients with lung cancer, QoL scores deteriorated in the experimental group more than in the standard-care group over the 16 weeks of observation.[29] Velikova et al[38] reported improvements in patient QoL scores at treatment initiation that were influenced by whether QoL was actually discussed during consultations.[38]

Psychological symptoms. Results were generally unsupportive of significant postintervention effects on anxiety and/or depression regardless of whether direct real-time[18,23] or indirect[20] patient feedback was made available to HPs. This was evident despite overall reductions in psychological distress over time.[27] Similarly, McLachlan et al[28] found no overall intervention effects on depression scores, but the subgroup of patients classified as moderately or severely depressed benefitted more from the intervention. Where significant improvements in anxiety or depression were reported,[42] these were small-to-moderate in magnitude (d = 0.15 to 0.42) and not universal across all assessment PROMs.

Supportive care needs. Five CTs provided generally unclear evidence; despite some small-to-moderate ES (d = 0.16 to 0.58) across domains of need, these were not always in favor of the experimental group (Appendix Table A3). The PROM intervention was no better than usual care in tackling needs of patients in two trials.[18,23] We found statistically significant between-group differences in 13 of 19 categories of perceived need[32] and sexual health concerns (d = 0.49)[22] in favor of the experimental group among patients with hematologic malignancies[32] and breast cancer,[22] respectively. In a non-RCT, patients receiving routine psychological screening reported more psychological, information, and physical/daily living needs, but not sexuality needs, at 6 months postbaseline compared with the unscreened cohort.[36]

Processes of Care

Medical decisions made/advice given/changes in treatment/referrals made. Despite being the outcomes most frequently investigated (Table 3), evidence

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Table 1. Summaries of the Methodologic Characteristics of the 24 Studies (26 articles) Reporting on the Use of PROMs As Interventions in Patients With Cancer Receiving Active Anticancer Treatment

Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Berry et al,[17] 2011	Outpatient clinic, US	Mixed cancer diagnoses (type, stage, and time since diagnosis); starting a new medical or radiation treatment regimen; RR, 62%; AR, 20%	47% MD; 23% RT; 30% SCT	327 (I); 333 (C)	262	Two-arm RCT	Intervention: Completion of intervention PROMs through ESRA-C and summaries available to HPs before consultation. Control: Completion of intervention PROMs through ESRA-C but summaries unavailable to HPs.	Processes of care; health service outcomes	Electronic interactive tool	Short term (same day as consultation visit)	No
Boyes et al,[18] 2006	Outpatient clinic, Australia	Mixed cancer diagnoses (type, stage, and time since diagnosis); attending clinic for the first time; RR, 65%; AR, 40%	65% SRG; 11% RT; 6% CT; 3% HT; 4% other ATR	42 (I); 38 (C)	4	Pilot longitudinal two-arm non-RCT	Intervention: Completion of touch-screen computer survey before consultation, and summaries available to consultants. Control: Completion of touch-screen computer survey before consultation but summaries unavailable to consultants.	Patient outcomes; processes of care	Electronic interactive tool; paper tool in clinic	Long term (three f/u visits)	No
Braeken et al,[19] 2011	Outpatient RT clinic, the Netherlands	Mixed early-stage cancer diagnoses; before first consultation; scheduled to receive > 10 fractions of RT; RR, 51%; AR, NR	100% RT	268 (I); 300 (C)	14	Two-arm clustered RCT	Intervention: Completion of intervention PROM before first and last consultation, and reports available to radiotherapists involved in care; the radiotherapists discussed patient needs and referred patients to psychosocial care providers. Control: Care as usual.	Processes of care	Paper tool in clinic	Long term (three assessments after baseline within 12 m)	No
Carlson et al,[20] 2010	Outpatient clinic, Canada	New diagnosis of breast (any stage) or lung cancer (any subtype or stage), attending clinic for the first time; RR, 89%; AR, 24%	2% SRG; 25% CT; 40% RT; 15% HT; 38% SC	391 (I); 378 (I); 365 (C)	NR	Longitudinal three-arm RCT	Intervention (full screening): Completion of intervention PROMs, summaries available to patient, and placed on the electronic medical record. Intervention (triage): Same as full screening, plus patients were invited to speak to a member of the psychosocial team; triage and referral options available to those requesting an appointment. Control (minimal screening): Completion of intervention PROM, but no summaries available to patients or placed on the medical record.	Patient outcomes; processes of care; health service outcomes	Electronic interactive tool; telephone or email f/u assessment	Long term (f/u assessment at 3 m)	Yes

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Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Cleeland et al,[40] 2011	Home, US	Mixed diagnoses (stage of disease) scheduled for thoracic surgery for primary lung cancer or lung metastases; RR, NR; AR, 21%	100% SRG	50 (I); 50 (C)	NR	Two-arm RCT	Intervention: Completion of intervention PROM at home twice a week through a telephone-based interactive voice response system; symptom information in the form of e-mail alert available to advanced practice nurse if symptoms met or exceeded preset severity alerts. Control: Completion of same intervention PROM at home, but no feedback available to clinicians.	Patient outcomes; processes of care	Electronic interactive tool at home; paper-based tool in clinic	Intermediate (seven f/u time points within 4-6 w)	No
Detmar et al,[21] 2002	Outpatient clinic, the Netherlands	Mixed diagnoses of advanced cancer (type and time since diagnosis); having received at least two cycles of palliative CT; RR, 71%; AR, 22%	100% CT	114 (I)‡; 100 (C)	10	Longitudinal crossover two-arm RCT	Intervention: Completion of intervention PROM and summaries available to both patients and physicians during consultation. Control: Usual care.	Patient outcomes; processes of care	Paper tool in clinic	Long term (three f/u visits after baseline)	Yes
Ganz et al,[22] 2000	Outpatient clinic, US	Breast cancer stage I or II diagnosed between 8 m and 5 y earlier; after completion of adjuvant CT or RT; RR, 77%; AR, 5%	56% HT	37 (I); 39 (C)	NR	Longitudinal two-arm RCT	Intervention: Daily completion of intervention PROM for 28 d before baseline; review of information and receipt of individualized intervention for three symptoms: hot flashes, vaginal dryness, and urinary incontinence; f/u assessment. Control: Daily completion of intervention PROM for 28 d before baseline; intervention was provided after f/u.	Patient outcomes; health service use	Take home paper tool/log book; paper tool in clinic	Long term (4-m f/u visit)	Yes
Girgis et al,[23] 2009	Home, Australia	Nonlocalized breast or colorectal cancer within 6 m of initial diagnosis; RR, 32%; AR, 6%	53% CT; 13% RT; 2% SRG; 31% other ATR	120 (I); 119 (I); 117 (C)	122§	Longitudinal three-arm RCT	Intervention (TCW): CATI using intervention PROMs and summaries available to TCW. Intervention (O/GP): CATI using intervention PROMs and summaries available to O/GP. Control: Usual care. CATI but no summaries provided to HPs.	Patient outcomes; processes of care	Telephone based	Long term (3 and 6 m after baseline)	No

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Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Hilarius et al,[24] 2008	Outpatient clinic, the Netherlands	Mixed cancer diagnoses (type and stage) at the start of CT treatment; RR, 83%; AR, 26.5%	100% CT	148 (I); 150 (C)	10	Longitudinal sequential two-arm cohort	Intervention: Completion of intervention PROM and summaries available to both patients and nurses during consultation. Control: Completion of intervention PROM, but summaries unavailable to nurses during consultation.	Patient outcomes; processes of care	Electronic interactive tool	Long term (four f/u visits)	Yes
Hoekstra et al,[25] 2006	GP practice and home, the Netherlands	Advanced breast, lung, or GI cancer with a life expectancy of 1-12 m; RR, 89%; AR, 32%	100% PSC	69 (I)‡; 77 (C)	89	Longitudinal two-arm clustered RCT	Intervention: Weekly self-assessment of physical symptoms at home through use of the intervention PROM. Control: Standard care.	Patient outcomes	Take-home paper tool/log book	Long term (every other month)	NR
Kearney et al,[41] 2009	Home and outpatient clinic, UK	Breast, lung, or colorectal cancer (any stage) at the initiation of a new course of CT treatment (any CT line); RR, NR; AR, 23%	100% CT	56 (I); 56 (C)	NR	Longitudinal two-arm RCT	Intervention: Completion of intervention PROM on mobile phone at home on days 1-14 post-CT administration; symptom information available to clinicians in real-time in the form of alerts (amber: mild/moderate severity; red: severe or life-threatening); clinicians contacted the patient within 48-72 h (amber) or 1 h (red). Control: Standard care (written and verbal information).	Patient outcomes	Electronic interactive tool at home; paper-based tool in clinic	Long term (four f/u time points within 12-16 w)	Yes
Klinkhammer-Schalke et al,[26] 2012	Inpatient surgery clinics, Germany	Newly diagnosed breast cancer (any stage) at discharge after initial surgical treatment; RR, 82%; AR, 15%	100% SRG	99 (I); 100 (C)	146	Longitudinal two-arm RCT	Intervention: Completion of intervention PROM by patient and health status form by physician; profiles available to experts; expert opinion available to coordinating practitioners who arranged QoL therapy consisting of up to five standardized treatments. Control: Completion of intervention PROM, but profiles and expert opinions unavailable to practitioners.	Patient outcomes; processes of care	Electronic interactive tool	Long term (f/u assessments at 3, 6, 9, and 12 m after baseline)	No

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Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Kornblith et al,[42] 2006	Home, US	Breast, colon, or prostate cancer (stages III or IV) within the first 2 m of active treatment; life expectancy of ≥ 12 m; RR, 82%; AR, 62%	100% ATR	96 (I); 93 (C)	NR	Longitudinal two-arm RCT	Intervention: Completion of intervention PROMs at home monthly for 6 m through TM in addition to EM; feedback available to oncology nurse if levels of distress above preset cut-off scores. Individualized discussion and treatment recommendation during f/u calls. Control: Standard care and EM only.	Patient outcomes; processes of care; health services outcomes	Telephone based	Long term (two f/u assessments at 6 and 9 m)	NR
Maunsell et al,[27] 1996	Inpatient clinic, Canada	Newly diagnosed breast cancer (any stage) after initial surgical treatment; RR, 89%; AR, 10%	67% RT; 30% CT; 46% HT	130 (I); 131 (C)	NR	Longitudinal two-arm RCT	Intervention: Brief psychosocial intervention by social worker postsurgery and f/u screening for psychological distress with intervention PROM; further intervention for highly distressed patients. Control: Brief psychosocial intervention by social worker postsurgery but no f/u screening.	Patient outcomes; processes of care; health service use	Telephone based	Long term (3 and 12 m)	NR
McLachlan et al,[28] 2001	Outpatient clinic, Australia	Mixed cancer diagnoses (type, stage, and time since diagnosis); having attended at least one consultation; RR, 59%; AR, 29%	26% SC; 32% CT ± RT; 5% other ATR	296 (I); 154 (C)	NR	Longitudinal two-arm RCT	Intervention: Assessment with intervention, PROM before consultation, and summary immediately available to consultants. Individualized management plan based on patient's responses. Control: Conventional clinical encounter and self-reported information unavailable to consultants.	Patient outcomes; processes of care	Electronic interactive tool	Long term (2 and 6 m after baseline)	NR
Mills et al,[29] 2009	Inpatient clinic, UK	Inoperable lung cancer, any subtype; RR, 51%; AR, 50%	61% CT; 17% RT; 16% CT plus RT; 6% SC	57 (I); 58 (C)	NR	Longitudinal two-arm RCT	Intervention: Weekly completion of intervention PROM at home; patients were asked to share information with any HP involved in their care. Control: Usual care.	Patient outcomes; processes of care	Take-home paper tool	Long term (16 w)	NA

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Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Nicklasson et al,[30] 2013	Outpatient clinic, Sweden	Incurable lung cancer (any subtype or stage) or mesothelioma with a life expectancy at the first clinic visit of ≥ 3 m; RR, 75%; AR, 1%	78% CT; 42% RT; 9% SC	85 (I); 88 (C)	22	Longitudinal two-arm RCT	Intervention: Completion of computerized intervention PROM before consultation; summaries were available to consulting physicians. Control: Completion of paper-and-pencil intervention PROM before consultation, but summaries were unavailable to consulting physicians.	Processes of care; health service outcomes	Electronic interactive tool; paper tool in clinic	Long term (8-12 w of f/u visits)	No
Rosenbloom et al,[31] 2007	Outpatient clinic, US	Advanced breast, lung, or colorectal cancer with a life expectancy of ≥ 6 m during CT treatment; RR, NR, and AR: 28%	100% CT	69 (I); 71 (C); 73 (C)	NR	Longitudinal three-arm RCT	Intervention: Assessment with intervention PROM followed by structured interview with treating nurse about patient's responses. Assessment control: Assessment with intervention PROM followed by feedback to treating nurses, but no interview. Full control: Assessment with outcome PROM, but no interview with or feedback to treating nurses.	Patient outcomes; processes of care	Paper tool in clinic	Long term (four f/u visits)	No
Ruland et al,[32] 2010	Inpatient and outpatient clinics, Norway	Newly diagnosed or recurrent hematologic malignancy at the start of treatment; RR, 90%; AR, 19%	68% CT; 34% SCT	75 (I); 70 (C)	NR	Longitudinal two-arm RCT	Intervention: Intervention PROM administered during inpatient, outpatient, and all f/u visits. Assessment summaries available to HPs. Control: Intervention PROM administered during inpatient, outpatient, and all f/u visits. Assessment summaries not available to HPs.	Patient outcomes; processes of care	Electronic interactive tool	Long term (≥ four follow-up visits)	NR
Sarna,[33] 1998	Outpatient clinics, US	Advanced lung cancer (any subtype); newly diagnosed; RR, 83%; AR, 56%	88% CT; 23% RT	48¶	NR	Longitudinal two-arm RCT	Intervention: Completion of intervention PROM and summaries available to staff nurses for discussion with the patient. Control: Completion of intervention PROM, but summaries unavailable to staff nurses.	Patient outcomes	Paper tool in clinic	Long term (six assessment points within a 6-m period)	No

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Table 1. Summaries of the Methodologic Characteristics of the 24 Studies (26 articles) Reporting on the Use of PROMs As Interventions in Patients With Cancer Receiving Active Anticancer Treatment (continued)

Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Taenzer et al,[34] 2000	Outpatient clinic, Canada	Primary, secondary, or metastatic lung cancer of any stage; an average of 51 m postdiagnosis; RR, 70%; AR, NR	NR% SC; NR% ATR	27 (I); 26 (C)	NR	Sequential pre- and postscreen, two-arm cohort	Intervention: Completion of intervention PROM before consultation and summaries provided to HPs. Control: Usual care.	Processes of care	Electronic interactive tool (I); paper tool in clinic (C)	Short term (same day as consultation)	No
Takeuchi et al,[35] 2011‖	Outpatient clinic, UK	Mixed cancer diagnoses (type and stage) at the start of treatment; RR, 65%; AR, 37%	100% ATR	100 (I); 46 (C); 52 (C)	28	Longitudinal three-arm RCT	Intervention: Completion of touch-screen intervention PROMs before clinic visit and feedback available to physicians. Attention-control: Completion of intervention PROMs before clinic visit, but feedback unavailable to physicians. Control: Standard care.	Processes of care	Electronic interactive tool	Long term (four time points within 6 m)	No
Thewes et al,[36] 2009	Rural outpatient clinics; home; Australia	Mixed cancer diagnoses (type and stage); newly diagnosed at the first clinic visit; RR, 81%; AR, 37%	76% SRG; 66% CT; 53% RT; 33% HT	43 (I); 40 (C)	NR	Sequential pre- and postscreen, two-arm cohort	Intervention: Completion of intervention PROM and feedback to nursing staff; patient assessment of problems and concerns if score above cutoff score. Control: Usual care; no intervention PROM administered.	Patient outcomes; processes of care	Paper tool in clinic; mailed f/u assessments	Long term (one f/u at 6 m after intervention)	NR
Trowbridge et al,[37] 1997	Outpatient clinic, US	Mixed diagnoses of recurrent or metastatic solid or hematologic cancers or sarcomas; RR, NR; AR, NR	100% ATR	160 (I); 160 (C)	13	Two-arm RCT	Intervention: Completion of intervention PROM before consultation and summaries provided to consultant; discussion of self-reported information. Control: Completion of intervention PROM before consultation, but summaries unavailable to consultant.	Patient outcomes; processes of care	Paper tool in clinic; mailed assessments	Intermediate (4 w after intervention)	No
Velikova et al,[38] 2004‖	Outpatient clinic, UK	Mixed cancer diagnoses (type and stage) at the start of treatment; RR, 65%; AR, 37%	76% CT; 21% BT; 2% HT; 1% f/u	144 (I); 70 (C); 72 (C)	28	Longitudinal three-arm RCT	Intervention: Completion of touch-screen intervention PROMs before clinic visit and feedback available to physicians. Attention-control: Completion of intervention PROMs before clinic visit, but feedback unavailable to physicians. Control: Standard care.	Patient outcomes; processes of care	Electronic interactive tool	Long term (four time points within 6 m)	No

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Table 1. Summaries of the Methodologic Characteristics of the 24 Studies (26 articles) Reporting on the Use of PROMs As Interventions in Patients With Cancer Receiving Active Anticancer Treatment (continued)

Author and Year of Study	Setting/Location	Patient Population	Type of Treatment*	No. of Patients†	No. of HPs	Study Design	Intervention/Control	Outcomes Assessed	Method of Administration of PROM	Evaluation of Effects	Patient Received PROM Feedback
Velikova et al,[39] 2010‖	Outpatient clinic, UK	Mixed cancer diagnoses (type and stage) at the start of treatment; RR, 65%; AR, 37%	76% CT; 21% BT; 2% HT; 1% f/u	144 (I); 70 (C); 72 (C)	28	Longitudinal three-arm RCT	Intervention: Completion of touch-screen intervention PROMs before clinic visit and feedback of results available to physicians. Attention-control: Completion of intervention PROMs before clinic visit, but feedback unavailable to physicians. Control: Standard care.	Processes of care	Electronic interactive tool	Long term (four time points within 6 m)	No

Abbreviations: AR, attrition rate; ATR, active treatment; BT, biological therapy; C, control; CATI, computer-assisted telephone interview; CT, chemotherapy; d, days; EM, educational materials; ESRA-C, Electronic Self-Report Assessment-Cancer; f/u, follow-up; GP, general practitioner; h, hours; HP, health care professional; HT, hormonal therapy; I, intervention; m, months; MD, medical; NA, not applicable; NR, not reported; O, oncologist; PROM, patient-reported outcome measure; PSC, palliative supportive care; QoL, quality of life; RCT, randomized controlled trial; RR, response rate; RT, radiotherapy; SC, supportive care; SCT, stem-cell transplantation; SRG, surgery; TCW, telephone caseworker; TM, telephone monitoring; UK, United Kingdom; US, United States; w, weeks; y, years.

*Percentages valid for total sample.

†Sample sizes of patients as randomly assigned (RCTs) and consented (non-RCTs) at baseline.

‡Physicians, rather than patients, were randomly assigned.

§Estimated as the total of 3 TCWs and 119 O/GPs.

¶Group sizes were not reported.

‖Articles are based on data from the same study; different sample sizes and outcomes are evaluated in each article.

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Table 2. Main Findings and Assessment of Risk of Bias in the 20 RCTs and Four Non-RCTs Identified for This Review

Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
RCTs											
Berry et al,[17] 2011	Intervention effects depended on whether a symptom/QoL issue was reported at threshold (P = .03). When reported at threshold, the intervention resulted in a 29% increase in the odds of the issue being discussed compared with the CG. This was evident for concentration, cognitive function, impact on sexual activities and interest, and social function.	No EG/CG differences (P = .35) for the average length of clinic visits. Clinicians agreed that the intervention was useful in identifying appropriate symptom/QoL issues (67.8%), guiding the interview (64.3%), promoting communication (50%), and identifying appropriate areas for referral (53.6%).	—	No	Low	Low	High	Unclear	Low	High	High
Braeken et al,[19] 2011	—	No significant intervention effects were observed for the total No. of patients referred to psychosocial care providers at 3 (P = .32), 9 (P = .22), or 12 m (P = .44). More patients in the EG brought up their need for psychosocial care during consultation (P = .04). EG were referred to social workers at an earlier stage than CG (P < .01). No significant intervention effect on improving patient-clinician communication about psychosocial problems; no effect on patients' satisfaction with communication with clinicians.	—	No	Unclear	Unclear	High	High	High	High	Low
Carlson et al,[20] 2010	Only a marginally significant main effect of study condition at follow-up for distress scores (P = .09). Significantly fewer patients in the triage group (36%) exceeded the distress cut off *v* 46% and 48.7% in full screening and minimal screening groups, respectively (P = .005). No EG/CG differences in anxiety or depression scores at 3 m overall or within either the lung or breast groups.	No differences between study conditions in referrals made to psychosocial care (P = .05) before or after follow-up. Receiving a referral was linked to less improvement on the distress score.	No differences between full screening and minimal screening in patient self-referrals (14.3% *v* 10.3%).	Yes	Low	Low	High	High	High	Unclear	Low

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Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Cleeland et al,[40] 2011	EG significantly greater reduction in overall symptom threshold events during the 4-week trial period (19% *v* 8%; $P = .003$). Symptom threshold events for pain, distress, disturbed sleep, shortness of breath, and constipation were more in the CG at week 4. No EG/CG differences in mean symptom severity changes at the end of 4 weeks. Greater reduction in mean symptom interference over time in EG ($P = .02$).	EG significantly more comfortable with intervention ($P < .03$) and more likely to rate the intervention as easy to use ($P < .01$) compared with CG. Both groups expressed satisfaction with the intervention and agreed for it to be used in routine clinical practice.	—	No	Unclear	Low	Low	Low	High	Unclear	High
Detmar et al,[21] 2002	No EG/CG differences at the fourth visit for any of the QoL scales. A significantly greater percentage of patients in the EG *v* the CG exhibited improvement over time in mental health (43% *v* 30%; $P = .04$) and role functioning (22% *v* 11%; $P = .05$).	Ten of 12 QoL issues were discussed more frequently in the EG, especially social functioning, fatigue, and dyspnea ($P < .05$). No EG/CG differences in exact or global physician-patient agreement, or in mean number of QoL-related patient management actions taken per patient. Patient and physician satisfaction was high in both groups. No differences in mean duration of visits. In the EG, the QoL summary profile provided an accurate picture of patient functioning and well-being (97%), and it would be useful as a standard part of the outpatient clinic procedure (87%).	—	No	Unclear	Unclear	Unclear	High	Low	Unclear	High
Ganz et al,[22] 2000	Change scores for menopausal symptoms ($P < .001$) and sexual functioning ($P = .02$) differed significantly between groups, with EG reporting fewer severe symptoms and better sexual functioning at follow-up. No EG/CG differences in terms of vitality ($P = .77$).	—	Women in both the EG and CG sought out additional information about their symptoms, at about the same rate. A similar percentage of women in each group received some form of psychological referral. Women in the EG used medications more frequently.	Yes	Unclear	Unclear	Unclear	Unclear	Low	Unclear	High

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Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Girgis et al,[23] 2009	No overall intervention effect was observed. Physical functioning was significantly improved at the third telephone interview for participants in the telephone caseworker group ($P = .01$) and there was a trend toward fewer participants with unmet needs ($P = .07$).	Patients in the telephone caseworker group were more likely to have indicated issues of need discussed ($P < .001$), referrals made ($P < .001$), and strong agreement that the intervention improved communication with their health care team ($P < .001$).	—	Yes	Low	Unclear	High	High	Low	Unclear	High
Hoekstra et al,[25] 2006	At the 2-m follow-up, the prevalence of symptoms was lower in the EG (prevalent differences 2.1%–24.3%) for nine of 10 symptoms (except coughing). Constipation and vomiting were significantly less prevalent in EG. Severity of fatigue, lack of appetite, shortness of breath, and nausea was lower in the EG (not significant). No EG/CG differences in severity of pain, coughing, sleeplessness, and diarrhea).	—	—	No	High	Unclear	High	Low	Low	Unclear	High
Kearney et al,[41] 2009	CG had significantly more reports of fatigue ($P = .04$) and significantly fewer reports of hand-foot syndrome ($P = .03$) than EG. No EG/CG differences in reports of vomiting/nausea, diarrhea, or sore mouth/throat. No EG/CG differences in severity and distress of symptoms, with the exception of higher severity ($P = .03$) and distress ($P = .03$) of hand-foot syndrome in EG.	—	—	No	Low	Low	High	Low	High	Low	High
Klinkhammer-Schalke et al,[26] 2012	At 6 m, 71% of patients in CG showed diseased QoL in at least one dimension. In the EG, this occurred in 56% of patients ($P = .048$). Relative risk was reduced 21% (95% CI, 0 to 37) and absolute risk was reduced 15% (95% CI, 0.3 to 29). The No. of diseased QoL dimensions per patient was lower in the EG at 6 m ($P = .035$). The percent of patients with zero QoL in at least one dimension at 6 m was 15% in the EG and 25% in the CG ($P = .124$).	At 3 m, coping strategies were applied more often but not significantly more in the EG than the CG ($P = .055$). Significantly more psychotherapy was given to women in the EG ($P = .005$) but the opposite was true for physiotherapy in the CG. At 6 m, the results were much more similar in the EG and CG.	—	Yes	Low	Low	High	High	Low	Low	Low

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Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Kornblith et al,[42] 2006	EG had significantly lower anxiety and depression at 6 m ($P < .001$). No differences on psychological distress, QoL, or comorbidities interfering with functioning. Significantly more patients in the EG had scores above cut off for depression/anxiety at 6 m (42% *v* 24%; $P = .041$).	No significant EG/CG differences in percent of physical symptom alerts. No differences in overall satisfaction with intervention (good/excellent, 88% *v* 74%). Significantly fewer patients in the EG rated the intervention very/extremely helpful in coping with an important problem ($P = .018$).	No EG/CG differences in use of mental health services at 6 m (9% *v* 12%).	No	Unclear	Unclear	High	High	High	Unclear	Unclear
Maunsell et al,[27] 1996	Participants' psychological distress levels decreased over the study period ($P < .001$), but no EG/CG differences. No EG/CG differences in physical health, functional status, social and leisure activities, return to work, or marital satisfaction.	No EG/CG differences in the mean No. of social worker contacts. CG and EG were very similar in total intervention time, proportion of contacts conducted in person, and mean duration of contacts conducted in person and by telephone during the baseline period. Use of psychosocial services, medical consultations, or other patient initiatives that might improve quality of life did not differ between groups.	The mean No. of visits was 2.4 and 6.1 among CG and EG patients, respectively, representing 48.9 and 119.6 min of social worker contact.	No	Low	Low	High	Unclear	High	Unclear	High
McLachlan et al,[28] 2001	No EG/CG differences in changes in psychological or health information needs, QoL, or psychosocial functioning between the baseline and follow-up assessments. For the subgroup of moderately/severely depressed patients, there was a significant reduction in depression for the EG relative to the CG at the 6-m assessment ($P = .001$).	No EG/CG differences ($P = .36$) in consultation times (17.7 min *v* 16.4 min) or levels of satisfaction ($P > .05$). For CG *v* EG patients, the percent of patients indicating their level of satisfaction was 95% *v* 98% for nursing care, 98% *v* 98% for medical care, 91% *v* 96% for information received about their illness and treatment, and 98% *v* 99% for overall satisfaction with the care received.	—	Yes	Low	Low	High	Low	Low	Unclear	High

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Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Mills et al,[29] 2009	Only a small but consistent difference in QoL was found between EG and CG. The EG had a poorer QoL in many domains. Two different QoL summary scores indicated a statistically significant between-group difference.	Only 23% of the diary group stated that they had shared their diary with any health professional. No intervention effects in communication, satisfaction with care, or the discussion of patient problems. EG discussed fewer topics with health professionals than the CG (not significant). Both groups reported high levels of satisfaction with their care, with no significant associations identified.	—	No	Low	Low	High	Low	Low	Unclear	Low
Nicklasson et al,[30] 2013	—	Issues regarding emotional functioning were more frequently discussed in the EG by doctors or patients taken together ($P = .015$). No EG/CG differences in physical/role, social, cognitive functioning, or global health. Pain, dyspnea, fatigue, and anorexia were somewhat more frequently discussed in the EG (not significant). Medical/technical statements were more frequently raised in the CG ($P < .05$). Length of doctor-patient conversations was similar in the EG and CG ($P = .77$). No. of diagnostic and therapeutic interventions for emotional and social concerns was higher in the EG.	Planned outpatient visits were similar between EG and CG (327 *v* 323).	No	Unclear	High	High	Low	Low	Unclear	Low
Rosenbloom et al,[31] 2007	No statistically significant differences across the three study conditions in QoL over time ($P > .05$). For all patients, QoL essentially did not change over the course of the study.	No significant differences across the three study conditions in general satisfaction and satisfaction with communication over time ($P > .05$). For all patients, satisfaction essentially did not change over the course of the study. No significant group differences ($P > .05$) in clinical treatment changes between the three conditions.	—	No	Unclear	Unclear	High	High	Low	Unclear	High

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Table 2. Main Findings and Assessment of Risk of Bias in the 20 RCTs and Four Non-RCTs Identified for This Review (continued)

Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Ruland et al,[32] 2010	Symptom distress in the EG decreased significantly over time in 11 (58%) of 19 symptom/problem categories *v* two (10%) for the CG.	Significantly more symptoms were addressed in the EG patient charts *v* those of the CG. Need for symptom management support over time also decreased significantly more for the EG than the CG in 13 (68%) symptom categories.	—	No	Low	High	High	High	Low	Unclear	High
Sarna,[33] 1998	Symptom distress scores of the CG were higher than scores of the EG ($P < .001$). Chemotherapy status and group assignment were both strong predictors of distress scores. The no-chemotherapy subgroup showed greater levels of distress than the chemotherapy subgroup with the CG and EG groups.	—	—	No	Unclear	Unclear	High	Unclear	High	High	High
Takeuchi et al,[35] 2011; Velikova et al,[38] 2004; and Velikova et al,[39] 2010‡	Patients in the EG and attention-control group had better QoL than the CG ($P = .006$ and $P = .01$, respectively), but the EG and attention-control groups were not significantly different ($P = .80$). A larger proportion of intervention patients showed clinically meaningful improvement in QoL.	More frequent discussion of chronic nonspecific symptoms ($P = .03$) in the EG, without prolonging encounters. No effect on patient management ($P = .60$). Discussion topics were predominantly raised by patients/relatives, regardless of group. Clinic discussions were associated with severity of reported symptoms, but not with patient-reported functional concerns. EG patients rated their continuity of care as better than the CG in terms of communication ($P = .03$). Patients' evaluations of the intervention were positive.	—	No	Unclear	Unclear	High	Unclear	High	Unclear	High
Trowbridge et al,[37] 1997	No significant EG/CG differences in assessments of pain, pain regimens, and relief received at the 4-week follow-up.	Significant EG/CG differences in physicians' patterns of prescribing analgesics (25% *v* 14%; $P = .016$). No significant differences in the percentage of patients undertreated for pain (38% *v* 35%; $P > .05$).	—	No	High	High	High	High	Unclear	High	High

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Table 2. Main Findings and Assessment of Risk of Bias in the 20 RCTs and Four Non-RCTs Identified for This Review (continued)

Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
					Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
	Patient Outcomes	Processes of Care	Health Service Outcomes		Random Sequence Generation	Allocation Concealment					
Non-RCTs											
Boyes et al,[18] 2006	Patients in the EG with a debilitating symptom at visit 2 were less likely to report a debilitating symptom at visit 3 compared with CG ($P = .04$). No EG/CG differences in change in anxiety ($P = .09$) and depression scores ($P = .20$). No significant EG/CG differences in change in average No. of moderate or high psychological needs reported over time ($P = .82$).	For patients, the intervention was easy to complete, and they would be willing to complete the survey each time they visited the oncologist. Only three EG patients reported that their oncologist discussed the feedback report with them. Half of the medical oncologists (n = 2) reported that they discussed the feedback directly with their patients.	—	No	High	High	High	Low	High	Unclear	Low
Hilarius et al,[24] 2008	No significant effects were found in changes in QoL over time.	QoL-related topics discussed more frequently in the EG ($P = .02$). Nurses' awareness of patients' levels of daily activity, pain, and overall QoL was significantly better in the EG. The mean No. of QoL-related notations in the medical records was higher in the EG ($P < .05$). Modest effects were observed in patient management; no significant effects in patient satisfaction over time.	—	No	High	High	High	High	High	Unclear	Unclear
Taenzer et al,[34] 2000	—	In the EG, more QoL issues identified by the patient were addressed during the clinic appointment than in the CG ($P = .01$). Marginally more categories were charted and a trend toward more actions being taken was recorded in the EG. Patients reported being equally and highly satisfied regardless of study group.	—	No	High	High	High	Unclear	Low	Unclear	High

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Author and Year	Main Study Findings*			Guidelines Were Used to Guide Clinician Response	Risk of Bias†						
	Patient Outcomes	Processes of Care	Health Service Outcomes		Selection Bias		Performance Bias: Blinding Participants and Personnel	Detection Bias: Blinding of Outcome Assessment	Attrition Bias: Incomplete Outcome Data	Reporting Bias: Selective Outcome Reporting	Other Sources of Bias
					Random Sequence Generation	Allocation Concealment					
Thewes et al,[36] 2009	Participants in the screened cohort reported significantly higher levels of overall unmet needs ($P < .001$), psychological needs ($P = .02$), information needs ($P = .02$), and physical and daily living needs ($P = .04$) compared with the unscreened cohort. No differences on sexuality needs.	Screening did not significantly increase the rate of referrals to psychosocial staff of distressed individuals, but reduced time to referral.	—	No	High	Unclear	High	Unclear	Unclear	Unclear	Unclear

Abbreviations: CG, control group; EG, experimental group; m, months; min, minutes; QoL, quality of life; RCT, randomized controlled trial.
*Information on effect sizes (where calculation was permitted by availability of data) is available in Appendix Tables A2, A3, and A4 (online only).
†Specific explanations for all ratings are available from the authors.
‡Articles are based on data from the same study; different sample sizes and outcomes are evaluated in each article.

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Table 3. Classification of Study Outcomes According to the Three Prespecified Outcome Categories (n = 24)

Patient Outcomes			Processes of Care			Health Service Outcomes		
Classification	No. of Studies	%	Classification	No. of Studies	%	Classification	No. of Studies	%
Physical symptoms: prevalence and/or severity[18,22,25,32,37,40,41]	7	29.2	Patient actual use of the intervention PROM[25,29]	2	8.3	Health services use/ self-referrals[20,22,42]	3	12.5
QoL[21-24,26,28,29,31,38,42]	10	41.7	Duration of contacts with HPs[17-19,27,28,30,38]	7	29.2	Contact with HPs[27,30]	2	8.3
Psychological symptoms[18,20,23,27,28,42]	6	25	Patient engagement in self-care actions[27]	1	4.2			
Supportive care needs[18,22,23,32,36]	5	20.8	Patient outcomes discussed during consultation[17,19,21,24,29,30,34,35,38]	8	33.3			
Overall distress[20,31,33]	3	12.5	HP acceptability/evaluation of intervention[17-19,21,24,38,39]	6	25.0			
Overall physical health[27,42]	2	8.3	Patient satisfaction with care/communication with treating team[19,21,23,24,28,29,31,34,37,39,40]	11	45.8			
Working hours[27]	1	4.2	Patient outcomes addressed in patient records[32,34]	2	8.3			
Social support[27]	1	4.2	Medical decisions made/advice given/changes in treatment/referrals made[19-21,23,24,26,30,31,34,36,37]	11	45.8			
Social activity[27]	1	4.2	HP use of PROM information[38,39]	1	4.2			
Physical activity[27]	1	4.2	HP satisfaction with encounter with the patient[21]	1	4.2			
Marital satisfaction[27]	1	4.2	HP awareness of patient outcomes[21,24]	2	8.3			
			Patient satisfaction with intervention[19,21,24,36,39,40,42]	7	29.2			
			Impact of referrals on patient outcomes[20]	1	4.2			
			Perceived continuity and coordination of care[39]	1	4.2			
			Timing of referrals[19,36]	2	8.3			

Abbreviations: HP, health professional; PROM, patient-reported outcome measure; QoL, quality of life.

of intervention effects on actions taken as a result of PROM feedback becoming available to clinicians remains generally ambiguous (Appendix Table A4). No significant intervention effects were reported in the number of patients referred to psychosocial care[19,20,36] or in clinical actions taken.[21,24,31] Although at 3 months after the intervention women with breast cancer in the experimental group were offered counseling and psychotherapy services more often, at 6 months this difference disappeared.[26] When PROMs were used to increase physician awareness of patients' levels of pain, a significant change ($d = 0.41$) in analgesic prescription patterns was found to favor the experimental group.[37] During treatment for chest malignancies, significantly more patients in the experimental group received diagnostic and therapeutic services for emotional and social concerns,[30] but numbers of QoL-related actions taken per patient were similar across study groups.[34]

Patient satisfaction with care and/or communication with team. Regardless of study condition, patient remarks on satisfaction with care and/or communication with HPs were generally positive.[19,21,24,28,29,31,34,39,40] Though eight CTs[19,24,28,29,31,34,40] failed to show significant intervention effects (Appendix Table A4). In the studies in which postintervention gains were reported, the positive effects referred to greater satisfaction with emotional support in the palliative chemotherapy context,[21] greater satisfaction with patients receiving follow-up from oncology nurses rather than general practitioners (though differences from usual care were not examined),[23] and enhanced communication with physicians in the outpatient setting compared with standard care.[39]

Patient outcomes discussed during consultation. Regardless of patients' cancer type, significant postintervention increases over time in the frequency of discussions pertinent to patient outcomes during consultations were recorded.[35,38] The odds of such outcomes being discussed seemed to depend on whether these were reported at a level indicating a problem.[17] Though emotional problems tend to be discussed more often during consultations in the experimental group,[19] social and sexual functioning issues may be those on which the intervention proves most effective.[17] Still, the overall patient-physician communication may not significantly improve.[19] In the lung cancer population, significantly more symptoms were discussed and addressed during consultations,[34] but intervention effects on QoL discussions fell short of significance. Much greater intervention effects were reported in the context of palliative chemotherapy (Appendix Table A4),[21] regarding overall communication about dyspnea ($d = 0.40$ to 0.77)[21,24]; social functioning ($d = 0.49$) and fatigue ($d = 0.38$)[21]; and sleep problems ($d = 0.66$), constipation ($d = 0.40$), diarrhea ($d = 0.67$), and cognitive functioning ($d = 0.66$).[24]

HP acceptability/evaluation of intervention. Where addressed, intervention acceptability was moderate to high across all CTs (Table 2), with rates of perceived usefulness ranging from less than 50% to 68%. HPs felt obtaining an overall assessment of the patient was more helpful[21,38,39] to identify issues of concern[17,19,21,38] and to guide discussions with patients[17-19,24] rather than in communicating with patients[17,19] and in managing and enhancing the care provided.[18,38] Yet, in two similar CTs, all physicians[21] and nurses[24] agreed that the intervention facilitated patient-clinician communication. The ability of HPs to identify psychosocial concerns[19,21] and address difficult subjects such as sexuality issues[24] was also enhanced. Although actual changes in HP communication styles may not be seen even following the intervention,[19] physicians[21,39] and nurses[24] seem willing to continue using the PROM summary in everyday practice. Nurses significantly more frequently found PROM

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interventions beneficial[17] and felt that use of relevant information resulted in more efficient use of their time.[24]

Patient satisfaction with intervention. Overall satisfaction with intervention was evident for at least 80% of patients.[40,42] The PROM interventions were seen as easy to use[40] and a useful way for patients to describe their situation[39] and communicate important information to HPs.[19] Patients expressed their willingness to continue using it in routine care.[39,40] However, in the Kornblith et al[42] CT, percentages of patients rating the PROM intervention as very or extremely helpful in coping with an important problem were notably low and favored the control rather than the experimental group (37% *v* 14%; $d = 0.69$). More than 83% of patients regarded the PROM content important for them and its use necessary for all patients receiving treatment.[19,36] Moreover, almost all patients (93%) appreciated having been asked about their emotional well-being during treatment.[36] In the palliative care setting, patients agreed that the summary profile enhanced their physician's or nurse's awareness of their health problems (79% to 89%), and that it would be useful as a standard part of their consultations (87% to 99%).[21,24]

HP awareness of patient outcomes. In the context of palliative chemotherapy, no intervention effects were reported on the magnitude of patient-physician agreement about patients' physical, emotional, and social well-being and daily activities ($d = 0.09$ to 0.50; Appendix Table A4).[21] The only exception was greater agreement in ratings of social functioning in the experimental group, but this applied only to the subgroup of patients who reported moderate-to-severe problems.[21] Oncology nurses' awareness of daily activities, pain, and QoL was significantly higher in the experimental group during the fourth patient visit.[24] Positive intervention effects were reported in patient care documentation in the medical records of patients being treated for hematologic malignancies[32] and in the number of QoL issues charted in records of patients with lung cancer.[34]

Timing of referrals. One RCT revealed that PROM feedback resulted in significantly earlier postconsultation referral of patients in the experimental versus the control group by an average of three weeks.[19] In a sequential cohort trial of patient-distress screening, average time to referral in the unscreened cohort was 14 days compared with a considerably earlier referral of only 5 days in the screened cohort.[36]

Health Services Outcomes

Only five CTs explored the effects of the routine use of PROMs on HSOs (Table 3; Appendix Table A5), namely, numbers of patients making use of health services[20,22,42] and frequency of contacts with health professionals.[27,30] Ganz et al[22] reported only minimal use of services after referral to psychosocial care in women with breast cancer; whereas prevalence of cases in which patients sought professional help was similar irrespective of study group among newly diagnosed patients with lung cancer and breast cancer.[20] Among patients with advanced breast, colorectal, or prostate cancer, use of mental health services at 6 months after intervention was equally minimal regardless of study condition ($P = .34$).[42] In terms of frequency of patient-HP contacts, positive intervention effects were found among women with breast cancer[27] but not among patients with chest malignancies.[30]

DISCUSSION

We found only tentative evidence regarding the effectiveness of PROM interventions to improve the quality of care provided to patients receiving active anticancer treatments. We used strict systematic methods during identification[12] and risk-of-bias appraisal[13] of all trials included here. We included 24 CTs, which investigated a wide range of outcomes, thus producing a disparate set of data and indicating lack of consensus around the role of PROMs and the range of outcome measures in clinical practice. Evidence suggests that, irrespective of the context of chronic illness, the impact of PROMs on POs is weak.[9,44] Where possible, we calculated ES in an attempt to quantify the magnitude of these effects, and our findings indicate inconsistencies in the overall significance (statistical or clinical) and low-to-moderate intervention effectiveness. Importantly, efficacy of the CTs reviewed seems low, confirming findings from previous reviews.[5,9,44]

Contrary to the limited evaluation of HSOs, PoCs were the most frequently investigated outcomes in our sample of trials. Mixed findings emerged regarding medical decisions made or actions taken by HPs as a result of the availability of PROM data. Changes in HP practices fell short of significance and, where such changes were documented,[30,37] the associated ES were still small. It is unclear whether limited referral options, additional subjective HP assessments, or other health care–related factors influenced the use of PROMs in practice. Patient satisfaction with care did not improve significantly, possibly owing to the presence of ceiling effects. Moreover, achievable improvements in patient communication with HPs, especially regarding emotional health issues, were documented, but ES were quite small. Somewhat greater ES can be proposed with regard to the actual discussion of POs during consultations, particularly physical symptoms, but not necessarily around supportive care needs.[19]

Fewer than 30% of the CTs addressed the important question of whether the use of PROM interventions appeals to patients and HPs. Though HPs may view PROMs as useful toward a more comprehensive or systematic assessment, communication is not always enhanced. In addition, there is still limited (albeit positive) evidence about whether HPs wish PROMs to become routine practice. Whether patients can comply with the systematic use of PROMs during treatment and encounters with the clinical team is equally unclear. Despite limited evidence, including electronic systems to enhance data collection and management, as well as use of clinical algorithms to support clinicians in the management of identified areas for intervention, might potentially increase adherence to and acceptability of PROM-enhanced clinical assessments.

Current data also suggest that patient physical symptoms and distress may be more amenable to improvement after PROM interventions than QoL, supportive care needs, or psychological symptoms. Even with the exception of the few studies that examined the use of health services by patients or contacts with HPs, important aspects of an intervention's applicability, such as patient safety or cost-effectiveness and cost-efficiency, are yet to be included as potential end points to encourage policy makers to consider making changes in the way cancer care is provided. Despite this lack of evidence, the Department of Health in England is aiming to extend the use of PROMs in a wider range of conditions in that country's National Health Service,[45] which would include cancer care.

Finally, measurement bias interfering with the effects of PROM interventions documented in this review should also be considered. Arguably, not all tools used in the delivery of interventions were originally developed as PROMs, which might have affected the reliability of reported outcomes and their subsequent interpretation. In addition, the psychometric robustness of the PROMs used to deliver and/or evaluate intervention effects is questionable and might have interfered with its ability to capture the actual magnitude of such effects. Similar comments can be made regarding sources of bias, such as absence of randomization or uncertainty about whether clinicians did use information generated by PROMs during consultations, which may have further affected the trials' internal and external validity and adversely affected credibility of available evidence.

Our search strategy was purposefully inclusive, with an aim to include all relevant literature. However, it was limited to the most common bibliographic databases, as well as to peer-reviewed articles

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and reports published in the English language only. In addition, the gray literature was not searched. Owing to the vast heterogeneity in the studies included, a meta-analytic synthesis was not feasible. Unavailability of data also prevented us from calculating ES for some of the included studies. However, such cases were equally distributed across statistically significant and nonsignificant findings or across the different outcome categories; hence, we are confident that the associated reporting bias has not greatly affected our conclusions.

More research is necessary on the effects of PROM interventions on health outcomes across different types of cancers and treatment modalities. The use of PROMs in clinical practice seems to be most effective in increasing patient satisfaction with communication about emotional concerns. Discussion of POs during consultations may increase and, in some studies, is associated with improved symptom control, increased supportive care measures, and patient satisfaction. Additional patient-related outcomes could be usefully addressed in future trials, including perceived self-care self-efficacy, social activity, work limitations, or survival. Patients and HPs are willing to engage in the routine use of PROMs during anticancer treatment. However, it is paramount that PROM intervention implementation is effective and incorporates strategies that increase patient adherence to the actual use of PROMs and HP engagement in the active incorporation of PROM feedback during encounters with patients.[44] Consensus is also required on the standardization of PROMs to be used in future trials. Finally, dedicated research is required to support the cost-effective use of PROMs in clinical practice regarding patient safety, clinician burden, and health-services usage. This is an important area of consideration, particularly in times of increasing demands on health care.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Appendix

Table A1. Electronic Databases Searched and Search Terms Used

Electronic Databases	Search Terms Used
Medline (1946 to May 2012)	1. exp controlled clinical trial/
EMBASE (1974 to May 2012)	2. exp randomized controlled trial/
CINAHL (inception to May 2012)	3. 1 OR 2
PsycINFO (inception to May 2012)	4. exp neoplasms/OR cancer*.mp. OR neoplasm*.mp. OR carcinoma*.mp. OR oncol*.mp. OR malignan*.mp. OR tumor*.mp. OR tumour*.mp. OR leukemia*.mp. OR leukaemia*.mp. OR sarcoma*.mp. OR lymphoma*.mp. OR melanoma*.mp. OR blastoma*.mp.
PBSC (inception to May 2012)	5. 3 AND 4
	6. (patient reported outcomes OR patient reported outcome OR patient based outcome OR patient reported outcome measure$).mp.
	7. inventory.ti. OR inventory.ab.
	8. instrument*.ti. OR instrument*.ab.
	9. measure*.ti.
	10. self report*.ti. OR self report*.ab.
	11. 7 OR 8 OR 9 OR 10
	12. 6 OR 11
	13. 5 AND 12
	14. Remove duplicates from 13
	15. Limit 14 to abstracts
	16. Limit 15 to English language

NOTE: Search strategy as conducted in Ovid Medline.
Abbreviations: ab, abstract; CINAHL, Cumulative Index to Nursing and Allied Health Literature; exp, term explosion; mp, free text search for a term; PBSC, Psychology and Behavioral Sciences Collection; ti, title.

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Table A2. Intervention and Outcome Assessment PROMs Used in the 24 Studies Reviewed (n = 26 articles)

Author and Publication Year	Intervention PROM(s)	Outcome Assessment PROM(s)*	Same Intervention/Outcome PROM(s)
Berry et al,[17] 2011	SDS EORTC QLQ-C30 Pain scale PHQ-9 SSS	Audio-recorded consultations Author-developed questionnaire regarding clinic visit duration; clinician evaluation of the intervention	No
Boyes et al,[18] 2006	Physical symptoms scales HADS SCNS-SF31	Physical symptoms scales HADS SCNS-SF31 Patient/clinician acceptability survey	Yes, plus additional PROMs
Braeken et al,[19] 2011	SIPP	Medical records Intervention evaluation inventories	No
Carlson et al,[20] 2010	DT and problem list PSSCAN part C	DT and problem list PSSCAN part C	Yes
Cleeland et al,[40] 2011	MDASI	MDASI Author-developed form for patient evaluation of the intervention	Yes
Detmar et al,[21] 2002	EORTC QLQ-C30	Audio-recorded consultations COOP WONCA Medical records Author-developed fatigue scale Patient Satisfaction Questionnaire C Physician satisfaction with communication SF-36 Patient/physician evaluation of the intervention survey	No
Ganz et al,[22] 2000	Daily diary symptom cards CARES (sexual summary scale)	Daily diary symptom cards CARES (sexual summary scale) RAND Vitality Scale	Yes, plus additional PROMs
Girgis et al,[23] 2009	HADS EORTC QLQ-C30 SCNS-SF34 NA-ACP	HADS EORTC QLQ-C30 SCNS-SF34 NA-ACP Patient perceptions of improved communication	Yes, plus additional PROMs
Hilarius et al,[24] 2008	EORTC QLC-C30 EORTC LC13 EORTC BR23 EORTC CR38	Self-report communication questionnaire COOP WONCA Chart audit PSQ-II SF-36 FACT-L/C/BCS Patient/nurse evaluation of the intervention questionnaire	No
Hoekstra et al,[25] 2006	The Symptom Monitor	The Symptom Monitor	Yes
Kearney et al,[41] 2009	Author-developed symptom questionnaire integrating the CTCAE grading system and the CSAS (electronic version)	Author-developed symptom questionnaire integrating the CTCAE grading system and the CSAS (paper-based version)	Yes
Klinkhammer-Schalke et al,[26] 2012	EORTC QLC-C30 EORTC BR23	EORTC QLC-C30 EORTC BR23 Medical records	Yes, plus additional PROMs
Kornblith et al,[42] 2006	HADS EORTC QLQ-C30 MOS-SSS	HADS EORTC QLQ-C30 MOS-SSS GDS-SF OARSQ, physical health subscale Utilization of mental health and psychosocial services scale GSRE Patient satisfaction with research program	Yes, plus additional PROMs

(continued on following page)

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Table A2. Intervention and Outcome Assessment PROMs Used in the 24 Studies Reviewed (n = 26 articles) (continued)

Author and Publication Year	Intervention PROM(s)	Outcome Assessment PROM(s)*	Same Intervention/Outcome PROM(s)
Maunsell et al,[27] 1996	GHQ-20	GHQ-20 Social Support Questionnaire LES LWMAT PSI Perceptions of health and worries about health Number of visits to HP Medical records	Yes, plus additional PROMs
McLachlan et al,[28] 2001	CNQ-SF EORTC QLQ-C30 BDI-SF	CNQ-SF EORTC QLQ-C30 BDI-SF Patient satisfaction survey	Yes, plus additional PROMs
Mills et al,[29] 2009	EORTC QLQ-C30 EORTC LC13	FACT-L TOI subscale PQLI Utilization of diary Patient/clinician communication checklist Patient satisfaction with care survey	No
Nicklasson et al,[30] 2013	EORTC QLQ-C30 EORTC LC13	Audio-recorded consultations Medical records	No
Rosenbloom et al,[31] 2007	FACT-G	FLIC Brief POMS-17 PSQ-III Clinical treatment changes survey	No
Ruland et al,[32] 2010	Choice ITPA	Choice ITPA Chart audit	Yes, plus additional PROMs
Sarna,[33] 1998	SDS	SDS	Yes
Taenzer et al,[34] 2000	EORTC QLQ-C30	PDIS Exit interview Medical record audit	No
Takeuchi et al,[35] 2011	EORTC QLQ-C30 HADS	Audio-recorded consultations	No
Thewes et al,[36] 2009	DT SPHERE-Short	Medical records SCNS-SF34 Satisfaction with intervention, Likert scales	No
Trowbridge et al,[37] 1997	Pain inventories	Pain inventories PMI Chart audit	Yes, plus additional PROMs
Velikova et al,[38] 2004	EORTC QLQ-C30 HADS	Audio-recorded consultations FACT-G Physician use of QoL information checklist	No
Velikova et al,[39] 2010	EORTC QLQ-C30 HADS	MCQ Satisfaction with care, single-item scales Intervention evaluation questionnaires	No

Abbreviations: BDI, Beck Depression Inventory; Brief POMS-17, Brief Profile of Mood States-17; BR-23, Breast Cancer 23 Module; CARES, Cancer Rehabilitation Evaluation System; CNQ-SF, Cancer Needs Questionnaire–Short Form; COOP, Dartmouth Primary Care Cooperative Information Functional Health Assessment; CR-38, Colorectal Cancer 38 Module; CSAS, Chemotherapy Symptom Assessment Scale; CTCAE, Common Toxicity Criteria Adverse Events; DT, Distress Thermometer; EORTC-LC13, European Organisation for Research and Treatment of Cancer–Lung Cancer Module 13; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer–Core Quality of Life Questionnaire, version 3.0; FACT-G, Functional Assessment of Cancer Therapy–General; FACT-L/C/BCS, Functional Assessment of Cancer Therapy–Lung/Colorectal/Breast Cancer Subscale; FLIC, Functional Living Index Cancer; GDS-SF, Geriatric Depression Scale–Short Form; GHQ, General Health Questionnaire; GSRE, Geriatric Schedule of Recent Experience; HADS, Hospital Anxiety and Depression Scale; HP, health professional; ITPA, interactive tailored patient assessments; LC-13, Lung Cancer 13 Module; LES, Life Experiences Survey; LWMAT, Lock-Wallace Marital Adjustment Test; MCQ, Medical Care Questionnaire; MDASI, MD Anderson Symptom Inventory; MOS-SSS, Medical Outcomes Study–Social Support Survey; NA-ACP, Needs Assessment for Advanced Cancer Patients; OARSQ-Physical Health, Older American Resources and Services Questionnaire–Physical Health; PDIS, Patient Satisfaction Questionnaire; PHQ-9, Patient Health Questionnaire–9; PMI, Pain Management Index; PQLI, Palliative Care Quality of Life Index; PROM, patient-reported outcome measure; PSI, Psychiatric Symptom Index; PSQ-III/II, Medical Outcomes Study–Patient Satisfaction Questionnaire III/II; PSSCAN Part C, Psychological Screen for Cancer–Part C; QoL, quality of life; RAND, Research and Development; SCNS-SF31, Supportive Care Needs Survey–Short Form 31; SCNS-SF34, Supportive Care Needs Survey–Short Form 34; SDS, Symptom Distress Scale; SF-36, Medical Outcomes Study 36-Item Short Form Health Survey; SIPP, Screening Inventory of Psychosocial Problems; SPHERE-Short, Somatic and Psychological Health Report–Short form; SSS, Subject Significance Scale; TOI, Trial Outcome Index; WONCA, World Organization Project of National Colleges and Academics.

*If no specific PROM was used, method of assessment is reported instead.

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Table A3. Evaluation of PROM Intervention Effects on Patient Outcomes

Outcome	ES (*d*)	95% CI*†	Effect Characterization‡
Menopausal symptom distress	−1.18	−1.68 to −0.67[22]	+
Prevalence			
Anxiety	−0.07	−0.41 to 0.27[23]	±
Depression	−0.15	−0.73 to 0.43[23]	±
Overall supportive care needs	−0.20	−0.46 to 0.06[23]	±
	0.58[36]		+
Need for help			
Psychological needs	−0.16	−0.73 to 0.40[18]	±
	0.50[36]		+
Information needs	−0.29	−0.86 to 0.28[18]	±
	0.53[36]		+
Patient care and support	−0.47	−1.05 to 0.10[18]	±
Physical and daily living	−0.34	−0.91 to 0.24[18]	±
	0.46[36]		±
Sexual functioning	−0.49	−0.96 to −0.02[22]	+
QoL			
Role functioning	−0.04	−0.26 to 0.19[23]	±
	−0.12	−0.40 to 0.16[21]	±
Emotional/psychological functioning	−0.18	−0.41 to 0.05[23]	±
	−0.11[31]		±
	−0.20	−0.48 to 0.07[21]	±
	0.10	−0.25 to 0.44[42]	±
Cognitive functioning	−0.05	−0.27 to 0.18[23]	±
Social functioning	−0.01	−0.24 to 0.22[23]	±
	−0.04[31]		±
	−0.07	−0.35 to 0.21[21]	±
Physical functioning	−0.16	−0.39 to 0.01[23]	±
	−0.12[31]		±
	−0.04	−0.32 to 0.24[21]	±
	−0.20	−0.55 to 0.15[42]	±
Physical and functional well-being	−0.41	−0.95 to 0.14[29]	±
Mental health	−0.10	−0.38 to 0.18[21]	±
Vitality	0.08	−0.38 to 0.54[22]	±
	−0.08	−0.36 to 0.20[21]	±
Bodily pain	−0.07	−0.35 to 0.21[21]	±
Nausea	−0.16[31]		±
Hardship owing to cancer	−0.05[31]		±
Overall QoL	−0.05	−0.28 to 0.17[23]	±
	−0.14[31]		±
	−0.59	−1.16 to −0.01[29]	+
	−0.35	−0.70 to −0.001[26]	+
	−0.04	−0.38 to 0.31[42]	±
Severity			
Fatigue	−0.37	−0.77 to 0.04[25]	±
	−0.25	−0.63 to 0.12[41]	±
Pain	0.04	−0.36 to 0.44[25]	±
Lack of appetite	−0.04	−0.44 to 0.36[25]	±
Shortness of breath	0.05	−0.35 to 0.45[25]	±
Sore mouth/throat	0.32	−0.05 to 0.69[41]	±
Coughing	−0.37	−0.77 to 0.03[25]	±
Sleeplessness	−0.31	−0.71 to 0.09[25]	±
Hand-foot syndrome	0.42	0.05 to 0.79[41]	-
Nausea	−0.44	−0.84 to 0.04[25]	±
	−0.18	−0.55 to 0.20[41]	±
Constipation	0.24	−0.16 to 0.64[25]	±
Diarrhea	0.0	−0.40 to 0.40[25]	±
	0.06	−0.32 to 0.43[41]	±
Vomiting	0.33	−0.07 to 0.73[25]	±
	0.01	−0.36 to 0.38[41]	±
Anxiety	−0.09	−0.65 to 0.48[18]	±
	−0.05[20]		±
	−0.30	−0.65 to 0.04[42]	±

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Table A3. Evaluation of PROM Intervention Effects on Patient Outcomes (continued)

Outcome	ES (*d*)	95% CI*†	Effect Characterization‡
Depression	0.08	−0.49 to 0.64[18]	±
	−0.01[20]		±
	−0.15	−0.49 to 0.20[42]	±
Psychological distress	−0.09	−0.34 to 0.16[27]	±
	−0.42	−0.76 to −0.07[42]	+
Prevalence			
Fatigue	−0.07	−0.62 to 0.47[25]	±
	−0.29	−0.60 to 0.02[18]	±
	−0.20[41]		+
Pain	−0.33	−0.78 to 0.12[25]	±
Lack of appetite	−0.29	−0.74 to 0.15[25]	±
	−0.19	−0.55 to 0.18[18]	±
Shortness of breath	−0.06	−0.50 to 0.38[25]	±
Coughing	0.34	−0.11 to 0.79[25]	±
Sleeplessness	−0.40	−0.85 to 0.04[25]	±
Nausea	−0.10	−0.57 to 0.37[25]	±
	−0.06	−0.79 to 0.67[18]	±
	−0.10[41]		±
Constipation	−0.73	−1.29 to −0.17[25]	+
	−0.06	−1.60 to 1.49[18]	±
Diarrhea	−0.32	−0.90 to 0.27[25]	±
	−0.88	−2.10 to 0.37[18]	±
	0.01[41]		±
Vomiting	−0.98	−1.83 to −0.13[25]	+
	−0.05[41]		±
Skin rash	−0.06	−1.60 to 1.49[18]	±
Sore mouth	0.25	−0.58 to 1.08[18]	±
	0.06[41]		±
Metallic taste	−0.06	−1.17 to 1.05[18]	±
Hot flashes	0.75	−0.48 to 1.98[18]	±
Hand-foot syndrome	0.23[41]		+
Overall distress	−0.15[20]		±
Distress			
Vomiting	0.05	−0.32 to 0.42[41]	±
Nausea	−0.15	−0.52 to 0.22[41]	±
Diarrhea	0.0	−0.37 to 0.37[41]	±
Hand-foot syndrome	0.35	−0.02 to 0.72[41]	+
Sore mouth/throat	0.33	−0.05 to 0.70[41]	±
Fatigue	−0.31	−0.69 to 0.06[41]	±
Overall	−0.02[31]		±
	−0.16[20]		±
Health status	−0.01	−0.34 to 0.33[27]	±
	0.0	−0.34 to 0.34[42]	
Worry about health	−0.10	−0.39 to 0.20[27]	±
Working during assessment	0.01	−0.28 to 0.30[27]	±
Hours worked per week	−0.05	−0.30 to 0.20[27]	±
Household activities performed	−0.08	−0.33 to 0.17[27]	±
Engagement in social activities	−0.23	−0.48 to 0.02[27]	±
Engagement in leisure activities	0.14	−0.11 to 0.39[27]	±
Engagement in physical activities	−0.02	−0.27 to 0.23[27]	±
Marital satisfaction	0.0	−0.25 to 0.25[27]	±

NOTE. Negative ES denote more favorable outcomes (eg, less severity or better scores) for the intervention group, and vice versa. ES were not calculated for controlled trials that reported pre-intervention between-group differences in the outcome in question, or where no relevant data were available. Where data were available, but no such baseline comparisons were performed/stated, baseline scores/percentages were compared using two-tailed independent sample *t* tests, thus ensuring that postintervention scores were not a result of preintervention differences. When studies reported results at more than one time point, the final time point was used, thus ensuring independence of data; hence, each study contributed no more than one ES for a specific outcome.[14] For studies with more than one experimental group, separate ES were calculated if different intervention PROMs were used; however, if the same intervention PROM was used, one ES was calculated based on pooled experimental versus control effects. If a study indicated that the effect was nonsignificant but no statistics were provided, ES was entered as zero.

Abbreviations: ES, effect sizes; PROM, patient-reported outcome measure; QoL, quality of life.

*ES calculations were performed only in those studies for which enough data were available.

†Where no 95% CIs are reported, not enough data were available to calculate them.

‡Based on *P* values ($P < .05$) and direction; + favors the intervention group ($P < .05$); − favors the control group ($P < .05$); ± represents $P \geq .05$.

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Table A4. Evaluation of PROM Intervention Effects on Processes of Care

Outcome	ES (*d*)	95% CI*†	Effect Characterization‡
Action			
Enrolled onto medical trial	−0.15	−0.53 to 0.22[27]	±
Met with other survivors	−0.14	−0.41 to 0.14[27]	±
Participated in patient-support group	−0.02	−0.47 to 0.43[27]	±
Consulted treating oncologist	−0.22	−0.52 to 0.09[24]	±
Consulted family physician	−0.002	−0.33 to 0.32[27]	±
Consulted other physician	−0.10	−0.38 to 0.18[27]	±
Had consultation for CAM therapies	−0.18	−0.54 to 0.19[27]	±
Had psychiatric/psychological consultation	−0.02	−0.44 to 0.40[27]	±
Sought help because of feeling depressed/sad	−0.11	−0.41 to 0.19[27]	±
Had a confidant	−0.27	−0.67 to 0.13[27]	±
Participated in relaxation activities	−0.05	−0.43 to 0.32[27]	±
Made dietary changes	0.13	−0.14 to 0.41[27]	±
Discussed			
Nausea/vomiting	−0.06	−0.26 to 0.14[17]	±
	0.22	−0.08 to 0.52[24]	±
	0.02[38]		±
	−0.07	−0.41 to 0.27[21]	±
Appetite	−0.06	−0.24 to 0.13[17]	±
	−0.09	−0.41 to 0.22[24]	±
	−0.40[38]		+
	−0.34	−0.65 to −0.03[30]	+
	0.06	−0.25 to 0.37[21]	±
Insomnia/sleep problems	−0.05	−0.23 to 0.13[17]	±
	−0.66	−1.00 to −0.32[24]	+
	−0.64[38]		+
	−0.13	−0.50 to 0.24[21]	±
Pain	0.02	−0.16 to 0.19[17]	±
	−0.10	−0.39 to 0.20[24]	±
	−0.01[38]		±
	−0.05	−0.36 to 0.25[30]	±
	−0.30	−0.62 to 0.03[21]	±
Fatigue	0.0	−0.19 to 0.19[17]	±
	−0.13	−0.43 to 0.17[24]	±
	−0.34[38]		±
	−0.06	−0.36 to 0.25[30]	±
	−0.38	−0.69 to −0.07[21]	+
Bowel pattern	0.14	−0.05 to 0.33[17]	±
Constipation	−0.40	−0.72 to −0.08[24]	+
Diarrhea	−0.67	−1.04 to −0.30[24]	+
Concentration	−0.29	−0.64 to 0.07[17]	±
Appearance	0.19	−0.07 to 0.45[17]	±
Impact on sex	−0.58	−0.99 to −0.17[17]	+
Breathing/dyspnea	0.01	−0.18 to 0.19[17]	±
	−0.77	−1.22 to −0.33[24]	+
	−0.15[38]		±
	−0.18	−0.48 to 0.13[30]	±
	−0.40	−0.82 to 0.02[21]	±
Outlook	−0.05	−0.24 to 0.15[17]	±
Cough	−0.05	−0.24 to 0.14[17]	±
Fever/chills	−0.03	−0.21 to 0.15[17]	±
Depression	−0.12	−0.36 to 0.13[17]	±
Suicidal ideation	−0.26	−0.89 to 0.36[17]	±
Symptoms of illness	−0.07	−0.38 to 0.23[30]	±
	0.02	−0.52 to 0.56[29]	±
Physical functioning	0.03	−0.15 to 0.21[17]	±
	0.26	−0.10 to 0.63[24]	±
	−0.21[38]		±
	−0.18	−0.48 to 0.13[30]	±
	−0.98	−1.31 to −0.64[21]	+
	−0.05	−0.26 to 0.17[19]	±

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Table A4. Evaluation of PROM Intervention Effects on Processes of Care (continued)

Outcome	ES (*d*)	95% CI*†	Effect Characterization‡
Emotional functioning	−0.11	−0.28 to 0.07[17]	±
	0.05	−0.28 to 0.37[24]	±
	−0.24[38]		±
	−0.44	−0.75 to −0.13[30]	+
	−0.17	−0.48 to 0.14[21]	±
	0.26	−0.29 to 0.81[29]	±
	−0.19	−0.38 to −0.01[19]	+
Social functioning	−0.14	−0.37 to 0.08[17]	±
	−0.18	−0.59 to 0.23[24]	±
	0.19[38]		±
	−0.21	−0.51 to 0.10[30]	±
	0.05	−0.49 to 0.62[29]	±
	−0.49	−0.93 to −0.04[21]	+
	−0.16	−0.38 to 0.06[19]	±
Cognitive functioning	−0.08	−0.35 to 0.18[17]	±
	−0.66	−1.19 to −0.12[24]	+
	−0.33[38]		±
	0.0	−0.31 to 0.31[30]	±
	−0.36	−0.97 to 0.25[21]	±
Daily functioning	0.14	−0.22 to 0.50[24]	±
	0.38	−0.19 to 0.94[29]	±
Role functioning	0.01	−0.18 to 0.20[17]	±
	−0.15[38]		±
	0.33	−0.23 to 0.90[29]	±
	0.70	0.37 to 1.03[21]	-
Sexual problems	0.06	−0.16 to 0.28[19]	±
Impact on family relationships	0.30	−0.25 to 0.85[29]	±
Existential issues	0.0	−0.31 to 0.31[30]	±
Financial issues	0.10	−0.20 to 0.41[30]	±
	0.02	−0.53 to 0.58[29]	±
Medical/technical issues/effects of treatment	0.27	−0.04 to 0.57[30]	±
	0.23	−0.33 to 0.78[29]	±
Overall condition	0.37	−0.20 to 0.95[29]	±
Global QoL	−0.01	−0.24 to 0.21[17]	±
	−0.45	−0.76 to −0.14[30]	+
	0.10	−0.21 to 0.41[30]	±
No. of concerns/symptoms discussed during consultations	−1.09	−1.67 to −0.52[34]	+
	−0.41[38]		+
	−0.38	−0.66 to −0.10[21]	+
No. of concerns/issues charted on patient records by nurses	−0.54	−0.81 to −0.27[24]	+
	−0.68[32]		+
No. of concerns/issues charted on patient records by physicians	−0.33[32]		+
No. of concerns/issues charted on patient records by health professionals, mixed sample	−0.49	−1.04 to 0.05[34]	±
Average duration of contact	0.18	−0.07 to 0.43[27]	±
	−0.08	−0.24 to 0.09[17]	±
	0.12	−0.13 to 0.37[28]	±
	0.09[38]		±
	0.03	−0.27 to 0.33[30]	±
	0.09	−0.19 to 0.37[21]	±
Satisfaction with nursing care	−0.56	−1.40 to 0.28[28]	±
Satisfaction with medical care	−0.16	−1.16 to 0.84[28]	±
Satisfaction with information received	−0.50	−1.12 to 0.12[28]	±
	0.18	−0.36 to 0.72[34]	±
	0.03	−0.53 to 0.60[29]	±
Satisfaction with support/rapport/communication	0.0	−0.54 to 0.54[34]	±
	−0.07[31]		±
	−0.04	−0.61 to 0.53[29]	±
	−0.37	−0.65 to −0.09[21]	+
	0.13	−0.05 to 0.31[19]	±

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Table A4. Evaluation of PROM Intervention Effects on Processes of Care (continued)

Outcome	ES (*d*)	95% CI*†	Effect Characterization‡
Satisfaction with help received about important problems	0.69	0.20 to 1.17[42]	-
Satisfaction with involvement in decision-making	0.14	−0.42 to 0.71[29]	±
Satisfaction with HPs addressing patient needs	−0.35	−0.90 to 0.19[34]	±
	0.13	−0.44 to 0.69[29]	±
Overall satisfaction with care	−0.39	−1.92 to 1.15[28]	±
	−0.08[39]		±
	0.33[31]		±
	0.13	−0.44 to 0.69[29]	±
Overall satisfaction with intervention	−0.52	−1.03 to −0.01[42]	+
Intervention acceptability, comfortable with using the system	−0.49	−0.94 to −0.04[40]	+
Intervention acceptability, system easy to use	−0.59	−0.14 to −1.05[40]	+
HP satisfaction with clinical encounter	0.0[21]		±
HP action			
No. of actions taken/medical decisions made per patient	−0.40	−0.94 to 0.15[34]	±
	0.16[38]		±
	0.02[31]		±
	−0.32	−0.62 to −0.02[30]	+
Referred to psychosocial care or other provider	0.08	−0.27 to 0.42[19]	±
	−0.31	−0.87 to 0.26[36]	±
	−0.01	−0.31 to 0.28[24]	±
	0.11	−0.22 to 0.43[26]	±
	−0.32[20]		±
	0.04	−0.18 to 0.26[19]	±
Prescription of medication	0.26	−0.07 to 0.60[24]	±
	−0.41	−0.72 to −0.09[37]	+
Ordering tests	−0.11	−0.45 to 0.22[24]	±
Changing/stopping chemotherapy	−0.05	−0.38 to 0.27[24]	±
Offering counseling on managing health problems	−0.26	−0.65 to 0.14[21]	±
HP awareness of patient outcomes			
Physical	−0.13	−0.40 to 0.14[24]	±
	−0.21	−0.69 to 0.27[21]	±
Feelings	−0.16	−0.43 to 0.11[24]	±
	−0.13	−0.66 to 0.39[21]	±
Daily activities	−0.28	−0.55 to −0.01[24]	+
	0.09	−0.41 to 0.59[21]	±
Social activities	−0.09	−0.35 to 0.18[24]	±
	−0.50	−1.05 to 0.05[21]	±
Overall health	−0.20	−0.47 to 0.07[24]	±
	0.19	−0.27 to 0.64[21]	±
Pain	−0.54	−0.82 to −0.27[24]	+
	0.20	−0.34 to 0.74[21]	±
Fatigue	−0.15	−0.41 to 0.12[24]	±
	−0.18	−0.58 to 0.23[21]	±
QoL	−0.27	−0.54 to 0.0[24]	±
Prevalence of patients undertreated for pain	−0.07	−0.33 to 0.18[37]	±

NOTE. Negative ES denote more favorable outcomes (ie, more frequent discussion or better communication) for the intervention group and vice versa. ES were not calculated for controlled trials that reported preintervention between-group differences in the outcome in question or where no relevant data were available. Where data were available but no such baseline comparisons were performed/stated, baseline scores/percentages were compared using two-tailed independent sample *t* tests, thus ensuring that postintervention scores were not because of preintervention differences. When studies reported results at more than one time point, the final time point was used, thus ensuring independence of data. Hence, each study contributed no more than one ES for a specific outcome.[14] For studies with more than one experimental group, separate ES were calculated if different intervention PROMs were used; however, if the same intervention PROM was used, one ES was calculated based on pooled experimental versus control effects. If a study indicated that the effect was not significant but no statistics were provided, ES was entered as zero.

Abbreviations: CAM, complementary/alternative medicine; ES, effect sizes; HP, health professional; PROM, patient-reported outcome measure; QoL, quality of life.

*ES calculations were performed only in those studies for which enough data were available.

†Where no 95% CIs are reported, not enough data were available to calculate them.

‡Based on *P* value ($P < .05$) and direction; + favors the intervention group ($P < .05$); − favors the control group ($P < .05$); ± represents $P \geq .05$.

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Table A5. Evaluation of PROM Intervention Effects on Health Service Outcomes

Outcome	ES (*d*)	95% CI*	Effect Characterization†
Patient use of psychological referrals	−0.10	−1.02 to 0.82[22]	±
Self-referrals	−0.20	−0.44 to 0.04[20]	±
Patient contacts with health professional	−0.85	−1.10 to −0.59[27]	+
	−0.15	−0.45 to 0.15[30]	±
Patient use of mental health services	0.18	−0.45 to 0.82[42]	±

NOTE. Negative effect sizes denote more favorable outcomes (eg, more frequent use of service or more contacts) for the intervention group and vice versa. ES were not calculated for controlled trials that reported preintervention between-group differences in the outcome in question or where no relevant data were available. Where data were available but no such baseline comparisons were performed or stated, baseline scores/percentages were compared using two-tailed independent sample *t* tests, thus ensuring that postintervention scores were not because of preintervention differences. When studies reported results at more than one time point, the final time point was used, thus ensuring independence of data. Hence, each study contributed no more than one ES for a specific outcome.[14] For studies with more than one experimental group, separate ES were calculated if different intervention PROMs were used; however, if the same intervention PROM was used, one ES was calculated based on pooled experimental versus control effects. If a study indicated that the effect was nonsignificant but no statistics were provided, ES was entered as zero.

Abbreviations: ES, effect size; PROM, patient-reported outcome measure.

*ES calculations were performed only in those studies for which enough data were available.

†Based on *P* value ($P < .05$) and direction; + ($P < .05$ favors intervention group); − $P < .05$ favors control group); ± ($P \geq .05$).

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